DEPARTMENT OF HEALTH AND HUMAN SERVICES

91536d

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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July 13, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-71

Morre L. Dean, President
Adventist Health Walla Walla General Hospital
1025 South Second Ave.
P.O. Box 1398
Walla Walla, Washington 99362

WARNING LETTER

Dear Mr. Dean:

We inspected your firm, Adventist Health-Walla Walla General Hospital located at 1025 South Second Ave., Walla Walla, Washington 99362, on June 21, 2001. During that inspection our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680 as follows:

1. Failure to properly label CPD whole blood, and Fresh Frozen Plasma with an expiration date appropriate for the product [21 CFR 610.53(c)] in that:

   a. You labeled CPD whole blood with a 35-day expiration date. The regulations clearly list the expiration date for CPD whole blood as 21 days.

   b. You failed to follow the blood bag manufacturer's instructions for a 21-day dating period for whole blood in CPD anticoagulant.

   c. Your SOP calls for use of CPDA-1 anticoagulant, not CPD anticoagulant for your whole blood collection bags. CPDA-1 anticoagulant has a 35-day expiration dating period if stored at proper temperatures.

   d. The whole blood label, attached to the collection bag for donor '[redacted]', collected on June 13, 2001, had both the CPDA-1 label as well as a CPD whole blood label.

The unit was actually collected in CPD anticoagulant; however, the expiration date used was for 35 days.

e. Your fresh frozen plasma (FFP) lists the storage temperature of -18° to -20° centigrade. On June 21, 2001, the temperature was observed to be -17.5° centigrade. During the week of May 29-June 4, 2001, the recording charts show the temperature at -17° centigrade. Your SOP states that "FFP is stored at -18°C to -20° C. When stored continuously at this temperature range the FFP can be used until the date of expiration listed on the packaging." No corrective action was taken and no modification to the expiration date was made.

2. Failure to store fresh frozen plasma at the proper temperature [21 CFR 640.34(b)] in that during the week of May 29-June 4, 2001, the recording charts show the temperature at -17° centigrade and on June 21, 2001, the temperature was observed to be -17.5° centigrade. No corrective action was taken.

3. Failure to standardize and calibrate equipment used in the storage of blood and blood components [21 CFR 606.60(a) and (b)], in that:

   a. The [redacted] digital thermometer was last calibrated on February 12, 1995. Electronic thermometers require monthly calibration.

   b. There are no records of the calibration of the [redacted] recording thermometer and daily temperature checks revealed as much as a 5 °C different between the recorder thermometer and the internal thermometer, used for daily comparisons. Since neither thermometer was standardized or calibrated it is not possible to determine which recording, if either, was correct. When temperatures were out of specification no corrective action was taken.

   c. The Temperature chart log for May 2001 documents that temperatures were out of specifications on at least 6 occasions. Five occasions when the temperature recorder showed the temperature was warmer than required (-17°C when the standard is between -18°C to -20°C), and one occasion when the temperature was -21°C (when the standard is no colder than -20°C).

   d. While the temperature recorder was reading -17°C the digital thermometer was showing a temperature of -22°C.

4. Failure to maintain written Standard Operating Procedures (SOP's) that include all steps in the collection, processing, compatibility testing, storage, and distribution of blood and blood products [21 CFR 606.100(b)(15)]. Your SOP's do not address how to, or when to, calibrate the [redacted] digital thermometers or the [redacted] Recording thermometers used in the blood bank.

5. Failure to follow the reagent manufacturer's instructions for use [21 CFR 606.65(e)] in that the [redacted] reagent, lot number 9D6355, used in crossmatching blood and blood components on June 19, 2001, had expired 19 days prior to it being opened and put into use in the blood bank. Our Investigator pointed out the fact that the reagent had expired on June 21, 2001, and the blood bank placed the reagent back in service. Quality Assurance records for this reagent clearly show that the reagent was expired prior to being placed in use.

6. Failure to maintain records concurrently with the performance of each significant step in the collection, processing, storage, and distribution of blood components including the identify the person performing the work, and the dates of various entries [21 CFR 606.160(a)(1)]. The "Blood Transfusion Report", which is used to document the destruction of blood and blood components, fails to record the date, method, and technologist who pulled the unit for destruction.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure, and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 22201 23rd Drive SE, Bothell, Washington 98021-4421, Attention: Bruce W. Williamson, Compliance Officer.

Sincerely,

Charles M. Breen
District Director